Shock to the System: How Alternative Dispute Resolution Can Foster Change in the Price-Setting of Mylan's EpiPen

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A twenty-one year old college student discovered she had a peanut allergy at the age of three, when a classmate shared peanut-butter crackers that led to a severe rash covering her body. Doctors quickly diagnosed this reaction as a peanut allergy. Over the years the allergy reaction strengthened, now she is allergic to not only peanuts but all nuts—even coconuts will produce a mild allergic reaction. She carries an EpiPen with her always, close friends carry one as well, and though she no longer lives at home her mother still has an EpiPen "just in case." She has only needed to use the EpiPen once; when she was a child and a waiter assured her the pieces of candy were "safe" (a word she uses to denote what foods are not contaminated and not life-threatening). In a matter of seconds, she began to feel her throat restrict and within minutes her life was saved as her father injected the epinephrine into her thigh. As Mylan increases the price on the drug she and others need, EpiPens may not be available when needed most.

I. INTRODUCTION

Modern healthcare relies on the use of many different pharmaceutical therapies. Physicians and patients have come to expect that their health will be enhanced by prescriptions, including antibiotics and other drug technologies. Obtaining and taking prescriptions has become so commonplace that consumers are rarely faced with the reasoning behind the price and value of the drug. It is only when the price becomes so high and hinders consumers' ability to utilize the necessary prescription that individuals are forced to gather, take actions, and play a role in the price-setting of prescription drugs.

Pharmaceutical companies hold great power within the healthcare industry.[1] The creation of life-saving medications, and subsequent patents create a controlling monopoly over the consumers and other parties that distribute pharmaceuticals.[2] Though many individuals purchase and re-purchase these drugs, it often feels as though the average consumer has little to no buyer power to assert against pharmaceutical companies. And, without buyer power, the pharmaceutical companies continue to set higher prices and consumers have no choice but to accept.

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[1] Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, Harvard Business Review, April 6, 2017, https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive.

[2] Aaron Xavier Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the Trips Agreement*, 45 HARV. INT'L L.J. 443, 446 (2004) (discussing that pharmaceutical industries treat their data as a trade secret in order to protect themselves from competition within the market).

Prescription drug pricing is complex and involves the input of many different parties throughout society. Consumers, insurance companies, and pharmaceutical manufacturers have differing and interacting interests, which are not all acknowledged in the current price of pharmaceuticals. For example, EpiPens provide a necessary utility to consumers but the high price makes it difficult for some individuals with life-threatening allergies to obtain this life-saving drug.[3] There has been recent widespread media attention on the continually climbing costs of prescription medications. Specifically, the drastic price increase of Mylan's EpiPen caused consumers to begin seeking solutions;[4] whether it is buying new generic epinephrine devices or joining a class action lawsuit against Mylan.[5]

While a class action lawsuit assists in aggregating a consumer base to increase buyer power, a more efficient resolution can be achieved with alternative dispute resolution (ADR) methods like arbitration and mediation. ADR focuses on complementing interests rather than competing positions and can utilize a neutral party that will help leverage the buyer power of consumers. Therefore, Mylan will perceive greater incentives to listen and change their pricing methods in dispute resolution methods than in traditional litigation methods. If consumers, through mediation and arbitration, can maximize buyer power by gathering as one unit and fostering the interests of all parties, cost-effective and productive prices of prescription drugs can be created.

A class action arbitration or mediation, rather than traditional binary litigation, allows drug manufacturers and the often-overlooked consumer to develop strategies to lower prescription drug prices while protecting the development costs of new and necessary drugs. The key to finding an effective solution in a class action against Mylan is utilizing a process that promotes flexibility, creativity, and more open communication. Mediation and arbitration employs a neutral to weigh sides of the case, but to aid and resolve the issue in a mutually-beneficial manner. Alternative dispute resolution opens communication between the parties, therefore this class can demonstrate to Mylan that their interests reflect the interests of the larger population that creates the demand for the EpiPen and if there is no price-reduction these

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[3] *See* Brad Tuttle, *Absurdly Expensive EpiPens Are Driving Families to Dangerous Lengths*, TIME MAGAZINE, July 7, 2016, http://time.com/money/4396467/epipen-prices-alternative/.

[4] Anna Davies, *Parents Are Getting Screwed by the Cost of* Epipens, NEW YORK POST, Aug. 22, 2016, https://nypost.com/2016/08/22/parents-are-getting-screwed-by-the-cost-of-epipens/.

[5] Brendan Pierson, *Mylan Hit with New Class Action Lawsuit over EpiPen Pricing*, REUTERS, April 3, 2017, https://www.reuters.com/article/us-mylan-nl-epipen-lawsuit/mylan-hit-with-new-class-action-lawsuit-over-epipen-pricing-idUSKBN1752CA.

consumers will simply purchase another generic product. A platform that has these characteristics allows consumers to speak directly to manufacturers (a feature which is not present in litigation) and to show that this group of consumers dictates the demand for this product, and they have immense buyer power over Mylan. The communication and open sharing of information is not present in litigation, and this is how the class of consumers can create and leverage buyer power in alternative dispute resolution processes to cause effective change in the healthcare industry.

This article begins with the many theories, method, and real-world examples of how prescriptions drugs are priced. The second closely examines Mylan's EpiPen and other epinephrine devices. The third section outlines the requirements of class action litigation and how alternative dispute resolution can seamlessly enter the process and provide a mutually-beneficial settlement. The last section concludes that alternative dispute resolution is a more economical and productive solution for all parties involved in Mylan's price-setting of the EpiPen.

II. THE COMPLEX BACKGROUND OF PRESCRIPTION DRUG PRICING

Participants within the healthcare system must concede that pharmaceutical companies are necessary in our modern world. Without pharmaceutical companies shouldering the immense costs of research and development of drugs and other technologies, many individuals would be at a loss for quality healthcare. Creating, testing, and following through the approval process is long and expensive, likely only feasible for organizations with large amounts of resources.[6] To incentivize the progress of modern medicine, the price of the prescriptions must cover at least the marginal[7] cost of production. Utilizing ADR in this class action is not meant to de-emphasize the role of manufacturers, but rather to find more long-term ways to reduce costs and protect benefits within society.

The values, and price tags of prescription drugs are compilations of different measures. The EpiPen is specifically ascribed value due to its unique design, lack of availability, and immense benefits. Consumers may not recognize the characteristics of the EpiPen that contributed to the price

[6] It costs nearly $3 billion to develop, approve, and bring a drug to market. *See* Rick Mullin, *Tufts Study Finds Big Rise In Cost Of Drug Development, Pharmaceuticals: Benchmark report sees the cost of bringing a drug to market approaching $3 billion*, CHEMICAL & ENGINEERING NEWS, Nov. 20, 2014, https://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html.

[7] Here, marginal meaning the amount difference between market price and cost of manufacture.

increase; ADR will open communication between a class of consumers and the manufacture to explain the present interests for production and sale of the product.

A. *Ascribing Value to Pharmaceutical Drugs*

Prescription medications are products of science, industry, and progress. But they are also deeply personal, human, and linked to enigmatic societal values. As the human population is living longer and healthier lives, prescriptions drugs are a part of a normalized human experience. A study by the Mayo Clinic found seventy percent of Americans take at least one prescription drug, and twenty percent of the population are on at least five prescription medications. [8] Clearly, consumers need and want these prescription drugs.

Prescription drugs are part of a normal, modern, healthcare regimen. Therefore discussion on the societal value and the related price tag of pharmaceuticals must be included in this article.

One theory of drug pricing reflects the advantages the product contributes to society known as the value-based pricing method.[9] Following this method, if a prescription drug provides a large value, society should be willing to pay a higher price.[10] For example, because Mylan's EpiPen provides a large value in saving lives for so many people with so many allergies; the value-based method asserts consumers should be willing to pay the large amount Mylan has set. Value-pricing is an accepted standard in the healthcare industry along with the trend of value-based insurance design. This insurance design is founded on the ideal that consumers are willing to pay for quality over quantity within the medical care field.[11] Whether or not patients are willing to spend more for high-quality services is of little import as health issues and needs arise, the consumer will pay whatever price is necessary to obtain care.[12] Both these theories indicate that consumers understand that the

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[8] Healthy Living, *Prescription Drugs: 7 Out Of 10 Americans Take At Least One, Study Finds,* THE HUFFINGTON POST, Jun. 20, 2013.

[9] Richard Manning, *The Role of Value And Cost in Prescription Drug Pricing*, LAW360, (Sept. 27, 2016, 12:36 PM), https://www.law360.com/articles/845069.

[10] *Id.*

[11] Robert Rubin, *Value Pricing for Drugs: Whose Value, What Price?,* HEALTH AFFAIRS BLOG, Mar. 28, 2016, http://healthaffairs.org/blog/2016/03/28/value-pricing-for-drugs-whose-value-what-price/.

[12] Morgan A. Muir et. al., *Clarifying Costs: Can Increased Price Transparency Reduce Healthcare Spending?,* 4 WM. & MARY POL'Y REV. 319, 320 (2013) (stating price demand within the healthcare industry is uniquely inelastic, as consumers will pay regardless of quality when a condition becomes serious).

dollar amount of the price sticker is about more than just the consumer's money—it is about knowing they will receive a necessary and meaningful value.

Price-setting values are complicated, however, by the myriad of conflicting values held by the many stakeholders in this industry. Consumers, as described, determine value by the benefits provided. But manufacturers and suppliers also consider a "novelty multiplier, the cost of development, a rarity multiplier, and the population burden of disease" which the prescription drug aims to treat.[13] If a drug is especially hard to develop and is especially novel, manufacturers are likely to say these characteristics necessitates a high price tag.[14] And because there are few checks and limitations to the price-setting of pharmaceuticals, the high value leads to high cost without a determination of any affordability benchmark.[15]

Pharmaceutical drugs can be measure and priced by the value providing to society.[16] An essential value is present when a drug is necessary to many people, and it might be unfair to price the drug following value and above the affordability benchmark. This is the scenario currently happening with the EpiPen;[17] a life-saving drug delivery device that is necessary for an expanding set of the population and is becoming more out of reach of the population as the price increases. Fifteen million Americans have food allergies, and food allergies among children have increased by fifty percent between 1997 and 2011.[18] The segment of the population searching for specific life-saving drugs is growing, and it is becoming more unethical to strictly follow the value-based method in setting high prices that make the product inaccessible for the consumers that need it most.

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[13] Robert Rubin, *Value Pricing for Drugs: Whose Value, What Price?*, HEALTH AFFAIRS BLOG (Mar. 28, 2016), http://healthaffairs.org/blog/2016/03/28/value-pricing-for-drugs-whose-value-what-price/.

[14] *Id.*

[15] Isaac D. Buck, *The Cost of High Prices: Embedding an Ethic of Expense into the Standard of Care*, 58 B.C. L. REV. 102, 123 (2017) (stating the high costs of healthcare is affected by overpriced pharmaceutical drugs and a regulatory system that allows pharmaceutical companies to charge prices in order to seek greater profits).

[16] Rubin, *supra* note 13. The ethical dilemma arises when the price of a drug is high, and the value provided by the drug is similarly high.

[17] Mylan's EpiPen is not the only drug that has experienced rapid and exponential price hikes, for a discussion regarding Martin Shkreli's 5000% price increase on Daraprim (a prescription used to treat HIV) see Isaac D. Buck, *The Cost of High Prices: Embedding An Ethic of Expense into the Standard of Care,* 58 B.C. L. REV 103,117-18 (2017).

[18] Food Allergy Research & Education, *Food Allergy Facts and Statistics for the U.S.*, FARE, https://www.foodallergy.org/facts-and-stats.

B. *Marketplace Pricing of Pharmaceutical Drugs*

Pharmaceutical companies have a large role and the greatest influence over setting the prices of prescription drugs. Even the federal government—the largest purchaser of prescription drugs—has no role in negotiations when buying drugs for Medicare.[19] Like the common consumer, the federal government is simply a "price-taker" and must accept the price set out by the drug companies.[20] It seems intuitive that a group that procures so much of the product should have greater buyer power, which could (and should) be leveraged against the manufacturers. But there is simply no opportunity for the federal government to exercise this buyer power.

In each section of Medicare, drugs are priced using different criteria and different processes. Medicare Part B regulates physician visits and similar non-hospital services; in this section drug pricing utilizes retroactive data to set future prices.[21] Prescription drug companies review the prices of drugs administered in doctor's offices by determining the average sale price of the drug from the previous quarter, and uses that to set a corresponding price for the prescription drug in the current quarter.[22] If the data shows physicians were charging a high price for the drug in the previous quarter, the price is likely to stay high or trend higher to cover rising costs of development.[23] While physicians are not setting the price for the prescriptions they prescribe within their clinics and hospitals (the prices are set by the manufacturers), the amount of prescriptions filled provides an indication to the manufacturer that consumers are willing to pay the retroactive price and future prices can be set accordingly.

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[19] John B. Kirkwood, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253, 262 (2016).

[20] *Id. See also* EZEKIEL J. EMANUEL, REINVENTING AMERICAN HEALTH CARE 220 (2014) ("Substantial research has shown that the prices paid for health care services in the United States are high.").

[21] Kirkwood, *supra* note 19, at 262.

[22] *Id. See also* Jeanne Whalen, *Why the U.S. Pays More than Other Countries for Drugs: Norway and Other State-Run Health Systems Drive Hard Bargains, and Are Willing to Say No to Costly Therapy*, WALL ST. J. (Dec. 1, 2015) (comparing the pharmaceutical pricing scheme in Norway (which includes negotiation between manufacturers and consumers) to the United States' price setting in Medicare Part B based solely on historical prices).

[23] Brendan Murphy, *Getting High on Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices*, 12 J. HEALTH & BIOMED. L. 37, 42 (discussing that patents are important to protect because there are high costs of investment and the development can be easily replicated by competitors).

Under Medicare Part B, pharmaceutical companies and private prescription drug plans (PDPs) negotiate with each other to set prices of the prescription drugs.[24] These are the only two parties allowed in the negotiation process, notably excluding the federal government. PDPs are able to wield their own buyer power over drug manufacturers and obtain discounts. Primarily, PDPs seek to lower prescription drug prices by promising to bring additional business to the pharmaceutical company.[25]

PDPs are most successful in negotiating prices with brand-name prescriptions for which there are at least a few close substitutes, or generic prescriptions.[26] Because the PDPs have other options to provide similar prescriptions to consumers, and the manufacturer knows this, the PDP has buyer power and the manufacturer will respond to negotiations to keep the PDPs' business.

PDPs utilize a formulary: a tiered list of the prescription drugs the plan covers which affects what prescriptions the consumer is mostly likely to purchase.[27] The tier a certain drug is on dictates how often a physician will prescribe that drug to patients, because of the amount of coverage the PDP provides that drug. The tier indicates how much of the cost of the drug the PDP will cover, affecting how much a consumer will have to pay out of pocket.[28]

PDPs negotiate with drug manufacturers by removing, adding, or altering the tier of prescription drugs on the list. If the PDP can show adding the specific drug to the formulary will increase the pharmaceutical manufacturer's business, the manufacturer is likely to accept the deal that involves a lower price.[29] If the prescription drug is already on the formulary, the PDP will negotiate that moving the drug to a different tier that offers lower co-pays, will lead to greater sales of the product.[30] Therefore, even though the drug may be priced lower than the manufacturer's optimal price, this tier placement will encourage more purchasing and profit to the manufacturer.

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[24] Kirkwood, *supra* note 19.

[25] *Id.* at 263. *See also* Lee B. Staley, *A Drug's Worth: Why Federal Law Makes It Hard to Pay for Pharmaceutical Performance*, 98 B.U. L. REV. 303, 317 (2018) (under Medicare Part D, PDPs negotiate with pharmaceutical manufacturers regarding the amount of access the company has to the health care providers' formularies, and how many consumers will then have access to the drug).

[26] Kirkwood, *supra* note 19, at 264.

[27] *Id.*

[28] *Id.* (placement on the formulary dictates the amount of copay, and drugs with lower copay lead to greater consumer sales).

[29] Kirkwood, *supra* note 19, at 264.

[30] *Id.* at 265.

As demonstrated in the negotiations between PDP and manufacturers; harnessing buyer power and demonstrating that lower prices will amount to sales can lead to successful negotiations for prescription drug consumers and pharmaceutical manufacturers alike.[31] This negotiation model under Part D is a satisfactory model for future interactions with other consumers. Allowing the average consumer to prove to manufacturers that lower prices encourage consumer purchase (like PDPs have done) creates buyer power for the class action plaintiffs in an ADR process.

Now looking at the manufacturer perspective, pharmaceutical companies justify high prices of prescription drugs because of the high prices of research and development.[32] Before the prescription drug reaches the consumer, the manufacturer shoulders the complex operation of scientific discovery and bureaucratic red tape. After completing intense and long-term research and development, a drug must pass clinical trials and receive approval from the Food and Drug Administration which can cost on average between five and a half billion dollars to almost six billion dollars;[33] additionally, there are a number of middlemen that must also receive compensation for their work.[34] For example, a distributor receives the drug from the manufacturer and charges a fee, then sells the drug to a pharmacy which receives its own fee.[35] All these fees must be satisfied in the sticker price on that drug. A consumer is not simply paying for the drug or drug delivery device, but also for these many processes. From scientific research to prescription pick-up, pharmaceuticals are an expensive business. These processes are essential, though, and must be incentivized so drug manufacturers continue the expensive methods of creating drugs with a proportionate price for the protection and benefit of society.

However, the price must also reflect the demand, need, and value from the consumer's perspective. Though the processes to put a drug on the marketplace are expensive, the price cannot be so exorbitant that those who need the drug cannot access it. An alternative dispute resolution process is more suitable to protect these costs and interests of the many parties, as drug manufacturers and consumers can explain these interests and create more

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[31] Kirkwood, *supra* note 19, at 266.

[32] Murphy, *supra* note 23, at 65.

[33] *Id. See supra* note 6 (past studies show it can also cost up to $3 billion dollars to bring a drug to market).

[34] Katie Thomas, *The Complex Math Behind Spiraling Prescription Drug Prices*, N. Y. TIMES, Aug. 24, 2016, http://www.nytimes.com/2016/08/25/business/high-drug-prices-explained-epipen-heart-medications.html?_r=0.

[35] *Id.*

flexible solutions through a process that is not as adversarial and positional as litigation.

III. MYLAN AND ITS PROFITABLE DRUG DELIVERY DEVICE

In order to understand how Mylan has become a large player within the pharmaceutical industry, some discussion on the history of the corporation is necessary. Mylan first came into existence in 1961, distributing medical and health products to medical professionals with the goal of providing access to affordable medicine.[36] Mylan has now grown into a company with more than 7,500 different products.[37] One of their products is the EpiPen, a self-injectable, epinephrine device.[38]

A. *The Innovative EpiPen*

Epinephrine is the first line treatment for a person that comes into contact with a life-threatening allergen and begins experiencing anaphylaxis.[39] Anaphylaxis is a common allergic response causing a spectrum of reactions from a rash, to a more immediate and harmful swelling of the throat that restricts breathing.[40] Specifically, for individuals with life-threatening allergies, the EpiPen is used before any other medical treatment to save their life. Many individuals have minutes after contact with the allergen before all breathing is restricted—usually not enough time for medical personnel to arrive and provide a dosage of epinephrine.[41] What makes Mylan's prescription drug so valuable is not only the life-saving—yet miniscule—dose of epinephrine,[42] but also the delivery device of the needle in the EpiPen.[43] This substantial, large needle is able to pierce through clothing quickly and

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[36] *See generally,* EPIPEN, https://www.epipen.com/en/about-epipen (last visited Apr. 20, 2018),

[37] *See generally,* Mylan, Global & U.S. Fact Sheets, https://s3.amazonaws.com/filecache.drivetheweb.com/mr5mr_mylan/177540/20170627_Mylan%20Global%20and%20US%20Fact%20Sheet.pdf (last visited Apr. 20, 2018).

[38] *See generally,* Mylan, http://www.mylan.com/en/products (last visited Apr. 20, 2018).

[39] EPIPEN, https://www.epipen.com/en/ (last visited Apr. 20, 2018).

[40] MAYO CLINIC, *Anaphylaxis,* https://www.mayoclinic.org/diseases-conditions/anaphylaxis/symptoms-causes/syc-20351468 (last visited Apr. 20).

[41] MAYO CLINIC, *Anaphylaxis,* https://www.mayoclinic.org/diseases-conditions/anaphylaxis/diagnosis-treatment/drc-20351474 (last visited Apr. 20).

[42] EPIPEN, https://www.epipen.com/en/about-epipen-and-generic/what-is-epinephrine (last visited Apr. 20, 2018).

[43] EPIPEN, http://www.epipen.co.uk/hcp/faqs/ (last visited Apr. 20, 2018).

can easily be administered by the person in anaphylaxis themselves, which is necessary as the EpiPen is designed for emergency situations.[44] This specific drug delivery device is what makes this drug so remarkable and so effective for consumers.

EpiPens have been in the marketplace since 1977, and Mylan first acquired this drug delivery system in 2007.[45] In 2007, the EpiPen cost fifty-seven dollars and the price has since risen to five hundred dollars or more.[46] In 2015, due to creative advertising and this price increase, EpiPen profits constituted forty percent of Mylan's total operating profits.[47] Though Mylan creates and sells over 1,000 products, this one drug constitutes almost half of the entire corporation's profits. Over these years, Mylan has not made significant changes or improvements in the drug or the drug delivery device, but has instead focused its efforts on massive campaigns to increase anaphylaxis awareness and preparedness.[48] Mylan fostered demand by partnering with organizations and businesses to stock EpiPens in schools and public places (like Disney theme parks and cruise ships).[49] Additionally, forty-seven states now encourage or require schools to stock EpiPens.[50] Additionally, manufacturers and physicians suggest people with life-threatening allergies carry two doses of epinephrine (two Epipens) with them at all times, if the person does not respond to the first dose or if it is incorrectly injected.[51]

B. *The Threat of Generic Epinephrine Devices*

For those with life-threatening allergies and organizations required by law to stock EpiPens, purchasing an EpiPen is not optional and they are forced to purchase at the new high costs. However, with recent media attention there have been more efforts to create a generic and less expensive epinephrine

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[44] EPIPEN, http://www.epipen.co.uk/hcp/faqs/ (last visited Apr. 20, 2018).

[45] Emily Willingham, *Why did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES, Aug. 21, 2016, http://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/ - d0710ab477af.

[46] *Id.*

[47] *Id.*

[48] Cynthia Koons & Robert Langreth, *How EpiPen Became a Hit*, BLOOMBERG BUSINESSWEEK, Sept. 28, 2015, at 21.

[49] *Id.*

[50] *Id.*

[51] *Id. See also* United Press International, *Allergic to Food: Carry Two EpiPens*, (Mar. 26, 2010) https://www.upi.com/Allergic-to-food-Carry-two-EpiPens/28851269659469/.

delivery device.[52] Consumers need to purchase epinephrine devices and if Mylan does not engage with the consumers to understand how the high price is hindering access, these consumers will purchase the drug elsewhere.[53] This provides consumers buyer power to negotiate with Mylan to lower prices, making alternative dispute resolution tactics an accessible path for a solution. Unlike litigation where the scope is only Mylan's actions, parties can discuss the presence of generic epinephrine prescriptions and how that will diminish Mylan's market.

IV. ADR IN CLASS ACTION LAWSUITS MODEL SOLUTIONS TO THE PHARMACEUTICAL INDUSTRY

Pharmaceutical companies, as the cost-bearer of production, view the value of the drug as including the work, time, effort, and creativity that went into development. However, the prescription-taker is more likely to see the human value as more important than the costs of bring the drug to market. Both values play into how prescription drugs should be priced, and it is only through alternative dispute resolution in which both interests are presented that both sides can find solutions. Litigation will not uncover these interests, or search for a way to find a mutually beneficial solution. Alternative dispute resolution methods focus on the conflicting and overlapping interests of the parties, providing an ample opportunity for consumers to amass buyer power (especially within a class action lawsuit), and having the opportunity for consumers to speak with the manufacturer about how they create the demand for the product and not have other generic options that will detract from Mylan's profits. A class action already provides the average consumer more buyer power, and ADR will capitalize on negotiation techniques to seek a lower price for the prescription medication.

Class actions are incredibly powerful vehicles to bring attention to large societal issues like racial discrimination or to achieve large-scale progress like prison reform or ending consumer fraud.[54] Many claims are likely to not be brought or see reward if pursued on an individual claim basis

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[52] Nathan Bomey, *CVS Targets EpiPen with Cheaper, Generic Version*, USA TODAY, Jan. 12, 2017, http://www.usatoday.com/story/money/2017/01/12/cvs-health-mylan-epipen-injector-impax-adrenaclick-donald-trump/96479776/.

[53] *Id.* (CVS offering a generic—and less expensive—version of the EpiPen will draw more consumers away from Mylan and allow other consumers to purchase epinephrine devices that previously could not afford Mylan's device).

[54] *See* Jean R. Sternlight, *As Mandatory Binding Arbitration Meets the Class Action, Will the Class Action Survive?*, 42 WM. & MARY L. REV. 1, 31 (2000).

but must be brought as a class action to see real action and resolution.[55] Whether a class action is pursued in litigation or alternative dispute resolution, the procedure remains similar. The difference lies in the process in achieving a mutually-beneficial outcome. ADR empowers the parties to create their own solution, affords each party opportunity to communicate, and come to an agreement that is unique. A judge may not be able to rule in a way that sets standards for future price-setting practices, but ADR combines a class of consumers to prove they have power and can create future change for the industry.

A. *The Use of ADR in Class Action Lawsuits*

Just as a class action lawsuit begins, the members of the class must meet the requirements of Federal Rule of Civil Procedure Rule 23(a) and 23(b).[56] Rule 23(a) requires the party show the class is numerous, the questions of law or fact are common to the class, the claims are typical of the claim of the class, and the representative parties will fairly and adequately protect the interest of the class.[57] Additionally, Federal Rule of Civil Procedure Rule 23(b) requires the class show that it would be incompatible for the individual plaintiffs to bring this claim themselves.[58] This can be satisfied where a unitary decision is appropriate to all the plaintiffs as they have suffered a similar harm.[59] The plaintiffs in this class action are likely to receive the necessary class certification as they have all suffered the same harm from the singular action of Mylan's expensive pricing of EpiPens. One decision, or agreement, regarding this claim is sufficient to resolve the issues throughout the class and the certification process can continue.

Though class actions are frequently utilized only in the litigation perspective, many jurisdictions require the parties attempt to resolve the dispute before it enters the courtroom.[60] This court-ordered ADR can uncover and define facts, complexities within the case, overlapping issues, and then quantify the possible value of the claims so when the case comes to litigation it is more simple for a judge to rule.[61] Other scenarios of court-ordered ADR

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[55] *Id.* at 80.

[56] *See* Fed. R. Civ. P. 23(a)–(b).

[57] Fed. R. Civ. P. 23(a).

[58] Fed. R. Civ. P. 23(b).

[59] Myron S. Greenberg & Megan A. Blazina, *What Mediators Need to Know about Class Actions: A Basic Primer,* 27 HAMLINE L. REV. 191, 205-06 (2004).

[60] *See* Fed. R. Civ. P. 23(a); *See also* Corby Pelto, *ADR: Building Bridges in Mass Tort Claims*, 57 DISP. RESOL. J. 10, 12 (2002).

[61] *Id.* at 12.

require the parties to utilize arbitration to not only clarify issues, but also to reach a settlement.[62] However, when the ADR process is mandated by the court, it is expected that there will be a high amount of supervision and cooperation between the parties, neutrals, and the court.[63] This creates many logistical concerns as the court will generate inefficiencies and remove flexibility for the parties.[64]

Once the claim is filed, a party to a class action need not wait to be ordered to utilize ADR but instead can elect to participate in a private and voluntary mediation which allows the parties to more effectively reach an agreement without entering a courtroom.[65] One of the main benefits of a private mediation is the choice parties have over who will function as their third-party neutral.[66] If the case encompasses a specific or complicated subject—like healthcare—it would be beneficial to invite a neutral that has expertise in the area. Rather than rely on a judge with general legal knowledge or be assigned a neutral that may not understand the industry, parties can choose a neutral that is knowledgeable and will assist in generating realistic options for settlement. With all the parties and neutrals empowered to act and equipped with correct knowledge, they can be more proactive, flexible, and creative as there is no court supervision or judge controlling the process.

Whether the ADR process is court-mandated or voluntary, any proposed class action settlement is subject to court approval.[67] The court is the guardian of the class and must ensure the settlement is fair to all members, and not just the representatives of the class.[68] Class members must be notified of the proposed agreement and given opportunity to object.[69] Once approved, the parties have a mutually-beneficial solution to which they have both contributed.

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[62] *Id.* A judge can require the parties to reach a settlement through a "mini-version of the case" or utilizing a less formal settlement discussion process.

[63] Greenberg & Blazina, *supra* note 59, at 214.

[64] Sternlight, *supra* note 54, at 51.

[65] *Id.* at 52-53.

[66] *Id.* at 27.

[67] Greenberg & Blazina, *supra* note 59, at 217.

[68] *Id.* at 218; *See Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 864-65 (1999) (rejecting the class action settlement proposal because it did not adequately meet the needs of many of the members of the class); *Amchem Prods Inc. v. Windsor*, 521 U.S. 591, 609 (1997) (holding that a class action may be formed for settlement purposes only, but still must meet the requirement of Federal Rule of Civil Procedure 23).

[69] Greenberg & Blazina, *supra* note 59, at 219.

1. *LEVERAGING BUYER POWER IN ALTERNATIVE DISPUTE RESOLUTION*

In order to find an efficient, longstanding solution to the high price of EpiPens, the plaintiffs in the class action suit against Mylan must create, aggregate, and leverage their buyer power. These consumers can do this by demonstrating they have demand for the product, options to buy the drug elsewhere if Mylan does not participate and this all will truly affect Mylan's profits.

Class action litigation and utilizing alternative dispute resolution in said class action fulfills the right of health care consumers to a fair and efficient process for resolving differences in their health care services.[70] In this modern age of health care service, consumers are becoming more involved in their health care decisions and controlling how they receive care. However, there are likely to be differences in the desires of consumers and providers giving rise to convoluted disputes. A national study conducted by the American Bar Association examined how creative processes (like alternative dispute resolution) were already working within the health care sector and whether it leads to satisfactory and imaginative solutions.[71] The study found that alternative dispute resolution is a useful resource as it relies on non-adversarial techniques, and aids to preserve partnerships between both parties in health plan-consumer disputes.[72] Preserving relationships between providers and consumers in the healthcare industry is necessary. If patients begin to distrust and avoid services, physicians, hospitals, and pharmaceutical companies will all suffer. An adversarial process can exacerbate the different positions instead of working to bridge gaps and mend relationships as dispute resolution processes seek to fulfill.

A drawn-out a vicious litigation process will create negative attention, and push target consumers away from supporting Mylan. Without the consumers, there is no demand for the product and Mylan will lose business from its drug that provides almost half of its profits.[73] Mylan needs to maintain a consumer base, especially as their competitors are planning to release a similar drug delivery device for a much lower price.[74] A class action suit poses

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[70] Naomi Karp & Erica Wood, *Medispute: Resolving Health Care Conflicts: Health Plan Internal Consumer Dispute Resolution Practices: Highlights from A National Study*, 5 J. HEALTH CARE L. & POL'Y 283, 286 (2002).

[71] *Id.* at 294-95.

[72] *Id.* at 323.

[73] Willingham, *supra* note 45.

[74] Matthew Herper, *In Rube Goldberg Price Scheme, EpiPen Competitor Auvi-Q to Be Free for Patients, $4,500 for Their Insurers,* FORBES (Jan. 19, 2017, 12:02 PM),

unique problems to the defendant, which can be capitalized by the plaintiffs in reaching a more satisfactory agreement. The defendant usually has an increased exposure to liability, as there is a concern over the media coverage and resulting public image, stockholder relations, or stock valuation.[75] This certainly happened to Mylan as its stock trading was traded at historically low valuations right before their Congressional hearing regarding the high price setting.[76] Unlike the plaintiffs, the defendant has large concerns about public image and ensuring a profit margin. By leveraging this weakness, and the already looming media coverage, the plaintiffs in the class action have an opportunity to force Mylan to engage and create an action that will better the corporate image.

Mylan has much to lose in this lawsuit process. This class action attacks the pricing scheme of the product that keeps the company successful. And a product that many people know, recognize, need, and value. The consumers in this class action, however, have very little to lose in pursuing a claim against Mylan. If Mylan does not cooperate, the consumer will buy CVS' new generic epinephrine device (or any number of generic prescriptions being created) and will not be subsequently harmed. Additionally, the class of consumers will not be harmed by media attention but will likely find support and be emboldened by other similarly-situated consumers throughout the county that are not a part of the class.

The consumers face numerous benefits in electing to participate in an alternative dispute resolution method, but Mylan can also benefit as it can temper much of the negative press Mylan has received. And ADR can possibly create positive attention if Mylan does work with the class of consumers to institute an option to provide inexpensive EpiPens, and this will ensure Mylan maintains and attracts consumers to buy their product.

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http://www.forbes.com/sites/matthewherper/2017/01/19/epipen-competitor-auvi-q-to-be-free-for-most-patients-but-cost-4500-for-insurers-in-rube-goldberg-scheme/#309d67bf339a.

[75] Greenberg & Blazina, *supra* note 59, at 203.

[76] Reuters, *Mylan's Stock Is the Lowest It's Been in 30 Years,* FORTUNE (Sept. 21, 2016), http://fortune.com/2016/09/21/mylan-stock-low/.

2. *LEVERAGING PERSONAL AND POLICY ARGUMENTS IN ALTERNATIVE DISPUTE RESOLUTION*

Healthcare presents unique complications as the core of the industry concerns decision involving life and death.[77] The industry relies on relationships between providers and consumers of healthcare, pharmaceutical companies, and medical device companies to enhance individuals' well-being.[78] Though all these players in the healthcare system need the other to survive and be successful, the varied interests often lead to a deeply entrenched positional, adversarial environment which alternative dispute resolution may be able to break down.[79] Traditional class action litigation, conversely, can foster the spectrum of positions and create greater divide in all the relationships.

With such a complex and emotional topic, alternative dispute resolution's goals of defining underlying facts in the dispute can address complicated issues that would otherwise be too polarizing to confront.[80] Instead of focusing on the positions these players hold—as in a traditional litigation process—alternative dispute resolution anchors solutions to the interests of the parties. Since this dispute revolves around access to life-saving medication, interests—especially for the plaintiff consumers—may not be rational and alternative dispute resolution can aid in breaking down this perspective to manageable, actionable interests.

ADR will help go beyond the positions and portray the emotional values in a way that can be understood by all parties. Neutrals can frame the plaintiffs' interest—their need to buy the lifesaving drug in numerous quantities and annually—as a method that will provide Mylan a steady stream of profit. Instead of focusing on one individual's allergy and need to inexpensively purchase an EpiPen, broadening the scope to show that a large population has deeply personal reasons to obtain this product will be a more powerful negotiation tactic. Just as PDPs negotiate with manufacturers to show a lower price will actually increase profit, an ADR neutral can analyze the consumer's emotional interests as incentives for Mylan to change its price-setting practices. A litigation process does not present an opportunity for the class of consumers to capitalize on this policy argument, as a judge must rule according to other questions of law. Since ADR does not only focus on the

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[77] Carrie Menkel-Meadow, *Scaling Up Deliberative Democracy as Dispute Resolution in Healthcare Reform: A Work in Progress*, 74 LAW & CONTEMP. PROBS. 1, 21 (2011).

[78] *Id.*

[79] *Id.*

[80] Greenberg & Blazina, *supra* note 59, at 212.

legal claims of each party, the consumers have more liberty to explain to Mylan their personal needs, and how that creates the demand for this product.

B. *Possible Hindrances in Utilizing ADR in Class Action Lawsuits*

As is the case with working in any large group of people, maintaining common goals and responsibilities is difficult in class action lawsuits.[81] Any relief sought must be acceptable both on an individual plaintiff basis and appropriate class wide,[82] and it is the court's responsibility to ensure that any proposed agreement provides a real and tangible benefit to class members.[83] This requirement may be problematic when utilizing negotiation practices and seeking more creative solutions to reduce the cost of the pharmaceutical for the class of plaintiffs. A creative solution to the price gouging of the EpiPen may not be quantifiable and therefore difficult for a court to evaluate. A settlement may not create present recovery for the class in terms of monetary damage, but a more efficient ADR settlement can promise future benefits in a lower price of the EpiPen.

Along the same vein, a large group of plaintiffs increases the likelihood of the presence of "bad-seeds" within the process.[84] This term is simply used to describe difficult people within the class that may hamper the success of reaching an agreement for the larger group;[85] bad-seeds could be hold-outs that will only accept a specific settlement, or an individual who truly believes that there are better options to be found.

Facilitators, mediators, and counsel must be aware of this risk within the group and learn how to combat and smooth the divides that are inevitable. This issue can be circumvented, but not without preparation.[86] Facilitators within the dispute resolution process can recognize the strongly held views and emotions of the difficult persons by involving them into more principled negotiations and claims.[87] For example, mediators can work with these bad-seeds in smaller groups and attempt to disarm them by encouraging a more

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[81] *Id.* at 205.

[82] *Id.*

[83] *Id.* at 217.

[84] Menkel-Meadow, *supra* note 77, at 25.

[85] *Id.*

[86] *See generally*, e.g., DOUGLAS STONE ET AL., DIFFICULT CONVERSATIONS: HOW TO DISCUSS WHAT MATTERS MOST (2000).

[87] Menkel-Meadow, *supra* note 77, at 28.

positive future process.[88] By working with these plaintiff members individually, divide or destruction within the class can be prevented.

Overall, the possible hindrances in utilizing alternative dispute resolution require more attention, time, and emotional energy. Not only must the plaintiff class attend to the conflicting interests of Mylan, but also the possible conflicting interests within their own group. However, the issues presented in utilizing alternative dispute resolution in this class action are not unique. The possibility of divide, conflicting interests, and procedural requirements of seeking court approval exist within all class action lawsuits. Therefore, because these problems are not unique, facilitators and mediators and counsel can be adequately prepared on how to handle the problems. A class action suit against a large pharmaceutical company does not present unsurmountable issues, and the ability to reach a beneficial and effective solution is probable despite the extra labor that it may require.

Though most class actions do not utilize alternative dispute resolution, the impediments in this process are uncommon and the benefits provided by ADR greatly outweigh the costs.

1. *MEDIATION PROMOTES CREATIVITY, BUT ENABLES BREAKDOWN*

Mediation is the use of a disinterested third party to assist the parties in reaching a voluntary settlement between parties.[89] A mediator, also called a neutral, assists the members of the party through a joint decisionmaking process.[90] Due to the informal and non-binding nature of the mediation process, it generally allows for more honesty and creativity in reaching a solution that is amenable to all disputants.[91] Those involved in mediation are more likely to support and stay true to the agreement as they have an emotional and mental commitment to the creation.[92] Mediation, rather than other forms of alternative dispute resolution and litigation, is more likely to be used when both parties believe there is a possibility of a future relationship.[93]

The conflict between the class of plaintiffs and Mylan is highly emotional and in need of a creative process to find a more permanent solution to the unconscionable pricing of the EpiPen. Having a designated neutral party involved within the decisionmaking process allows the affected consumers to

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[88] Menkel-Meadow, *supra* note 77, at 25.
[89] Greenberg & Blazina, *supra* note 59, at 212.
[90] *Id.*
[91] *Id.*
[92] *Id.* at 213.
[93] *Id.*

air the emotional effects of the high pricing. And if Mylan can respond to the underlying interests of the emotional reaction as interpreted by a neutral party in mediation, they can maintain this group of consumers.

Mylan may be more likely to engage in a mediation rather than litigation or another alternative dispute method because of its non-binding nature. This allows both parties to seek inventive options to lower the price of EpiPens and make them more accessible to consumers. With the knowledge that the company will not be forced to complete any one agreement, the Mylan representatives are more likely to be candid and be inventive. This allows the plaintiffs to gather more information about Mylan, and their pricing process. Any information garnered through the mediation can be leveraged towards more buyer power against the pharmaceutical company.

Another benefit of utilizing mediation is the mediator does not have an evaluative role. The mediator's purpose in the process is to facilitate communication, clarify interests, and assist in creating options.[94] The parties, rather than the mediator, will be challenged to work with each other to find an agreement. A possible solution which may be created in mediation is a process requiring Mylan to acknowledge the consumer perspective in setting the EpiPen price. Perhaps this could include the manufacturer consulting and seeking approval from certain consumer representatives, or creating a survey outlining quantifiable information demonstrating what consumers are willing to pay for this product. A judge in a traditional litigation setting could not make a ruling that incorporates these unique, creative, and forward-thinking options.

Though mediation is the ADR method that promotes the most creativity, the mediator has no duty to ensure a settlement is reached and therefore the parties have sole responsibility for negotiating a final agreement. If either side cannot agree to an option or cannot move past one issue, the entire process will break down and the parties will leave the table. Due to the inherently complex nature of a class action—the many individuals with many views and desires—arbitration, rather than mediation is the best option for the class and Mylan to reach an agreement.

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[94] *See* Greenberg & Blazina, *supra* note 59, at 212 (discussing how advocates argue that the mediation process enables parties to engage in a more user-friendly method for reaching a satisfying resolution).

2. *ARBITRATION PROVIDES STABILITY, RELIANCE, AND FLEXIBILITY*

Usually when mediation has proved unsuccessful, parties turn to arbitration where the neutral provides a decision after hearing arguments and evidence from both sides.[95] This decision can be binding and is left to the neutrals to formulate the agreement.[96] Unlike in mediation where the neutral is an active participant guiding and facilitating discussion between the two parties, the neutral in arbitration is passive and allows the disputants to command the conversation.[97] What arbitration lacks in creativity is made up for in the expediency of decisions; similar to traditional litigation without the costs and more flexibility.[98]

Arbitration can be useful in this class action because the situation is so convoluted. Involving a decisionmaker that is neutral and available to hear large amounts of information is an incentive to both parties involved. Mylan can discuss with the neutral the rationale of the pricing of EpiPen, which includes the research, development, unique design, and value it provides to consumers. Moreover, the neutral can learn how and why it is so important to the pharmaceutical company to continue receiving high profits from this product.

Likewise, the plaintiffs have ample opportunity to present their interests in purchasing EpiPens at a lower price. Arbitration allows consumers to exercise greater buyer power that normally is not available within the health care industry. In this ADR process, the plaintiffs need only convince one neutral individual rather than sway the opinion of the party holding the monopoly (unlike discussing this claim with only Mylan in mediation). The neutral decisionmaker, unlike Mylan, may be more likely to hear the emotional arguments of the consumers since their access to Mylan's product represents a true life or death decision in many cases.

Arbitration also allows for some distance between the parties that may prevent any further damage to the relationship.[99] This creates formality and stability that is usually only found in litigation proceedings. Knowing and understanding that the final agreement was created by a person who heard,

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[95] Greenberg & Blazina, *supra* note 59, at 212.

[96] *See* John W. Cooley, MEDIATION ADVOCACY 9 (1996); Greenberg & Blazina, *supra* note 59, at 213 (when an arbitration is binding, the decision is binding and enforceable. Conversely, nonbinding decisions are advisory only).

[97] Greenberg & Blazina, *supra* note 59, at 213; *see also* John W. Cooley, MEDIATION ADVOCACY 9 (1996).

[98] Greenberg & Blazina, *supra* note 59, at 213.

[99] *See Id.*

analyzed, weighed both arguments will provide a greater sense of justice to the parties. This is similar to litigation, but the arbitrator has more flexibility on the solution rather than just handing down a decision.

Though an arbitrator may not propose an agreement that incorporates the creative solution mentioned previously, whatever agreement is reached can be binding. The future actions or process decided upon will control the relationship between Mylan and the class, provide consumer protection while balancing the economics interests of the company. Again, this provides a similar sense of security and justice as litigation but in a more efficient and cost-effective manner.

Alternative dispute resolution processes, allows this specific class of plaintiffs more interaction and communication with a pharmaceutical company that even the federal government does not have with regarding drug pricing. Arbitration creates opportunity for greater communication, honesty, and openness that enables the consumer class to prove the scope of the demand they create for the product, which may incentivize Mylan to respond in order to maintain that demand and Mylan must respond in order to maintain this group of consumers.

V. CONCLUSION

Pharmaceutical companies have control over price-setting, and without leveraging buyer power, consumers will continue to be a price-taker within the healthcare industry. Prices will continue to rise, and necessary drugs will become priced out of the reach of the consumers that need them. Rather than litigation, alternative dispute resolution in this class action will demonstrate to Mylan and other pharmaceutical companies that consumers should be the focus of the industry, and companies will only ignore their consumers at their own financial peril.

ADR opens communication between the parties, allowing this class of consumers to prove they create the demand for the EpiPen and without their purchase, Mylan would lose many of its profits. Though mediation is the method most likely to lead to a creative and unique solutions, arbitration is most likely to lead to an actual settlement between the parties. An arbitrator will listen to both sides, weighing all legal and policy related arguments, and craft a binding solution without the monetary, and emotional costs of litigation.

The healthcare industry is a web of individuals, groups, organizations, and businesses centered around the patient and consumer. ADR in this class action invites the consumer to the table, puts the consumer at the center of the

healthcare field, and models how other facets of the health care industry can follow the pharmaceutical lead.